General

Guideline Title

Safe administration of systemic cancer therapy. Part 1: safety during chemotherapy ordering, transcribing, dispensing, and patient identification.

Bibliographic Source(s)

Leung M, Bland R, Baldassarre F, Green E, Kaizer L, Hertz S, Craven J, Trudeau M, Boudreau A, Cheung M, Singh S, Kukreti V, White R, Safe Administration of Systemic Cancer Treatment Expert Panel. Safe administration of systemic cancer therapy. Part 1: safety during chemotherapy ordering, transcribing, dispensing, and patient identification. Toronto (ON): Cancer Care Ontario (CCO); 2012 Jul 9. 75 p. (Evidence-based series; no. 12-12-1). [65 references]

Guideline Status

This is the current release of the guideline.

The EVIDENCE-BASED SERIES report, initially the full original Guideline, over time will expand to contain new information emerging from reviewing and updating activities.

Please visit the Cancer Care Ontario Web site for details on any new evidence that has emerged and implications to the guidelines.

Recommendations

Major Recommendations

Areas of Interest and Summary Recommendations

Within the main objective, the Working Group highlighted several areas of interest. Some of these areas encompass the entire process of chemotherapy administration, and some are specific to the planning and preparation stages. Each area of interest is presented below, followed by a summary of the recommendations. The justification for the recommendations and the link to supporting evidence can be found in Section 2 of the original guideline document.

Areas of Interest Encompassing the Entire Process of Chemotherapy Administration

Environmental Considerations

- Physical and staffing resources allowing the completion of tasks in an environment free from distractions and interruptions are fundamental to the safe administration of chemotherapy.
- Customized interventions to obtain a distraction- and interruption-free environment will need to be tested on a case-by-case basis.

Patient Identification

- The Working Group recommends that organizations should set up a process for patient identification such that patients are identified at entry in the system, and then at each step of the treatment process, by the different members of the healthcare team involved.
- This process should include the use of at least two identifiers, the first being the patient's full name and the second being the patient's date of birth, medical record number, or other patient-identifying information, and specifics about the methods for the proper identification of patients with language barriers or special needs.
- Patients should receive an identification wristband at entry to the organization, and this should be used during their stay in the organization while receiving treatment.
- If possible, a technology such as automated identification and data capture (e.g., barcoding, radiofrequency) should be used for patient identification. Institutions that use these technologies should have policies, procedures, and staff education in place so that workarounds that threaten patient safety using automated identification systems are avoided.

Information and Education for Patients and Their Families/Caregivers and Their Role in the Plan of Care

- The Working Group recommends that patients who are to receive or who are already receiving chemotherapy should be provided with oral and written information that enables them to comprehend the aims, effects, and outcomes of the proposed or ongoing treatment. Information should cover the following, at a minimum:
    - Diagnosis
    - Goals of therapy
    - Treatment process
    - Regimen, and its short and long term effects
    - Management of side effects
- The Working Group recommends that patients (or their substitute decision makers) should play a major role in preventing medication errors by being actively involved in all phases of the treatment process in a patient-centered model of care. Healthcare providers need to be open, receptive, and responsive to patient questions.

Computerized Prescriber Order Entry (CPOE)

- The Working Group recommends CPOE as the standard to reduce adverse events for protocols and orders. Where CPOE is not available, standardized, regimen-level pre-printed forms should be used to improve consistency and readability and to avoid prescription error. Handwritten orders are not acceptable.
- Protocol templates stored electronically should be in a read-only format to avoid unapproved alteration of the original. A process should be in place for the creation and upkeep of the templates. Access to the original protocol document should be restricted to authorized persons.

Checklists

The Working Group recommends checklists as a tool for the administration process when multiple, complex, mechanistic tasks are required.

Areas Specific to the Planning and Preparation Phases of Chemotherapy Treatment

Patient Assessment

- The Working Group recommends that organizations should have written protocols and procedures for patient pretreatment assessment by clinicians.
- A patient assessment prior to chemotherapy administration is the responsibility of the clinical team. The assessment for chemotherapy administration should include, but may not be limited to, the following:
    - Baseline observations, specific to the protocol
    - Patient history and treatment plan
    - Current medications, including alternative therapies
    - Presence of allergies or other hypersensitivity reactions
    - Patient performance status and physical findings that may impact on the treatment process
    - Patient weight, height, and body surface area
    - Laboratory results
    - Response to previous treatment and previous toxicities that may impact on treatment
    - Compliance with home premedication treatment
    - Assessment for and maintenance of access devices required for administration
    - Presence of psychosocial concerns

Tools for Patient Screening and Assessment

See Table 1 in the original guideline document for screening tools and web link to resources.

Parts of a Written Plan

- The Working Group recommends that a systemic treatment plan should be documented and available and should include other decisions made for the patient such as surgery and radiation therapy, as well as requirements related to nursing and allied healthcare staff. The plan should ideally be in a computer-generated format and should be part of or filed with the patient record at all times.
- Any change in the plan of treatment (i.e., a new protocol is initiated or a medication dose is changed), should be clearly documented on the treatment plan, noting the time the change was initially ordered.
- A copy of the treatment plan should be distributed to all facilities involved in the patient's care as well as the patient's primary care healthcare provider.

Treatment Scheduling Models: Same Day versus Non-Same-Day

- Non-same-day chemotherapy scheduling may be an appropriate option for many patients undergoing chemotherapy.
- Organizations should weigh the pros and cons of each scheduling model as it pertains to their environment, geographic challenges, and patient population.
- Individual patient circumstances should always be considered.

Pharmacy Practices: Chemotherapy Preparation and Delivery

- The Working Group recommends that good practices in chemotherapy preparation and delivery include the following:
  - Verification of the chemotherapy order and preparation.
    - Verifying a chemotherapy order should include a systematic check of all the components of the chemotherapy order and its preparation and dispensing. Verification and independent double checking processes should be regulated by oncology-specific policies and procedures and training and certification programs to maintain accuracy and quality.
    - Independent double checking at various points of the chemotherapy preparation process should be as frequent as possible. Independent double checking may still be required when CPOE is in place because of the possibility of major variations or deviations in protocol, protocols that are new or not yet built into the CPOE program, or complex calculations involved in chemotherapy preparation.
    - Independent double checking during the chemotherapy preparation process is ideally made by a second pharmacist or, depending on physical and staffing resources, by a pharmacy technician (Tech-Check-Tech procedure where one technician checks the order-filling accuracy of another), or by another healthcare professional with appropriate knowledge, skills and training to perform this function.
- Appropriate chemotherapy labelling (see Program in Evidence-based Care [PEBC] Evidence-based Series [EBS] 12-11: Patient Safety Issues: Key Components of Chemotherapy Labelling):
  - Labelling of outsourced drugs is still required. An analysis of labelling from outsourced products should be performed to ensure that it does not conflict with in-house products.
- Appropriate packaging and transportation of chemotherapy drugs and the education of personnel who handle chemotherapy drugs (see PEBC Special Report: Safe Handling of Parenteral Cytotoxics):
  - Chemotherapy should be packaged for dispensing and delivered in a manner that meets acceptable safety standards and reduces chances for confusion or patient errors.

Infusion Pumps

See Table 2 in the original guideline document for safety characteristics of various infusion pumps.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Cancer

Guideline Category

Management

Prevention

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Nursing

Oncology

Preventive Medicine

Intended Users

Advanced Practice Nurses

Health Care Providers

Hospitals

Nurses

Pharmacists

Physician Assistants

Physicians

Guideline Objective(s)

To provide guidance on processes, technologies, and devices for the prevention of errors during systemic cancer treatment administration in adult patients in areas that cut across the entire process and in the planning and preparation stages

Target Population

Adult patients who are going to receive chemotherapy treatment or who are already receiving chemotherapy treatment for cancer in hospital settings

Interventions and Practices Considered

1. Environmental considerations (distraction- and interruption-free environment)
2. Patient identification processes
3. Providing information and education for patients and their families/caregivers about treatment and their role in preventing medication errors
4. Use of computerized prescriber order entry (CPOE)

5. Use of checklists as a tool for the administration process when multiple, complex, mechanistic tasks are required
6. Use of written protocols and procedures for patient pretreatment assessment by clinicians
7. Tools for patient screening and assessment
8. Use of a documented systemic treatment plan
9. Treatment scheduling models: same day versus non-same-day
10. Pharmacy practices: chemotherapy preparation and delivery
11. Infusion pumps

Major Outcomes Considered

- Medication errors
- Missing doses
- Error rates
- Error detection rates
- Incidence of administration errors
- Nurses' compliance with protocol steps
- Number of interruptions/distractions
- Time saved
- Patient safety
- Potential adverse drug events rates
- Ability of the pharmacy to prepare chemo in time for appointments

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Question: What are the best strategies to reduce distractions and interruptions during chemotherapy administration?

Search Strategy

The Working Group searched the following electronic databases: MEDLINE, EMBASE, Cochrane, and CINAHL, their own files, and the references of included articles for citations of studies on strategies aimed to reduce distractions and interruptions during the process of identifying patients, prescribing, transcribing, dispensing and administering drugs. The search strategy for the Medline database with specific key terms is shown in Appendix 2A of the original guideline; this search strategy was adapted for the other databases.

Selection Criteria

The Working Group included systematic reviews or comparative studies that assessed strategies for reducing distractions and interruptions of healthcare personnel during the process of chemotherapy ordering, prescribing, transcribing, dispensing, identifying patients, and administration of the drugs. Systematic reviews or comparative studies were included if published in English from 2000 to 2010 December week 4.

Studies were excluded if they were not about strategies aimed at reducing healthcare personnel distractions and interruptions and if they were publication types such as editorials, comments, letters, and news.

The methodologist screened the titles and the abstracts. Full-text articles were retrieved in the library if the citations met the inclusion criteria or if the title and the abstract did not contain enough information to decide. A clinician member of the Working Group and the methodologist

independently reviewed the full text of the included citations against the selection criteria.

Question: What are the most effective technologies for patient identification? (wristbands, barcoding, radiofrequency identification systems, automated ID, data capture)

Search Strategy

The following electronic databases were searched: MEDLINE, Cochrane (Database of Abstracts of Reviews of Effects; Central Register of Controlled Trials; and Database of Systematic Reviews), EMBASE, CINAHL; the reference lists of included studies; and the Working Group's own files for citations of studies on patient identification technologies to prevent medical errors. The search strategy with specific key terms designed for MEDLINE is reported in Appendix 2B of the original guideline; this search strategy was adapted for the other databases.

Selection Criteria

Systematic reviews or comparative studies that assessed technologies used for wrong patient error prevention in medication administration, irrespective of the context were included. Studies were included if published in English from 2005 to 2010 August week 4.

Studies were excluded if they were not about technologies used for patient identification and if they were publication types such as editorials, comments, letters, news.

The methodologist screened the titles and the abstracts. Full text articles were retrieved in the library if they met the inclusion criteria or if the title and the abstract did not contain enough information to decide, and were reviewed.

Question: Are checklists effective in preventing medication-related adverse events during the administration of chemotherapy agents?

Search Strategy

The Working Group searched the following electronic databases: MEDLINE, EMBASE, Cochrane and CINAHL and their own files for citations of studies on the effectiveness of checklists in preventing medication errors. The search strategy for the Medline database with specific key terms is reported in Appendix 2C of the original guideline; this search strategy was adapted for the other databases.

Selection Criteria

The Working Group included systematic reviews or comparative studies that assessed the use of chemotherapy administration checklists for safety purposes. Studies were included if published in English from 1996 to 2010, November week 4.

Studies were excluded if they were not about the use of checklists for chemotherapy and if they were publication types such as editorials, comments, letters, and news.

The methodologist screened the titles and the abstracts. Full text articles were retrieved in the library if they met the inclusion criteria or if the title and the abstract did not contain enough information to decide.

Question: What is the most effective scheduling model for reducing errors in the administration of chemotherapy to cancer patients?

Search Strategy

The Working Group searched the electronic databases: MEDLINE, Cochrane (Database of Abstracts of Reviews of Effects; Central Register of Controlled Trials; and Database of Systematic Reviews), EMBASE, and CINAHL and HealthStar, and their own files for citations of studies on same-day versus non-same day scheduling for outpatient chemotherapy. The search strategy with specific key terms designed for MEDLINE and HealthStar is reported in Appendix 2D of the original guideline document; this search strategy was adapted for the other databases.

Selection Criteria

Systematic reviews or comparative studies that assessed same day versus non-same-day chemotherapy scheduling were included. Studies were included if published in English from 2000 to 2010 October Week 1.

Studies were excluded if they were not comparative, if the intervention was an alternative scheduling method and if they were publication types such as editorials, comments, letters, news.

The methodologist screened the titles and the abstracts. Full text articles were retrieved in the library if they met the inclusion criteria or if the title and the abstract did not contain enough information to decide and were reviewed.

Number of Source Documents

- Distractions and interruptions: 4 studies (3 full text articles and 1 abstract) were included.
- Patient identification technologies: 11 studies were included.
- Checklists: 1 study was included.
- Scheduling models: 1 article was included after full-text review.

See the study flow charts in the appendices of the original guideline document for additional detail.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Systematic Review: Distractions and Interruptions

Synthesizing the Evidence

The methodologist created evidence tables (see Appendix 2A in the original guideline document) and a narrative synthesis of the evidence was performed. A statistical pooling of the results was not possible because the studies were too heterogeneous.

Systematic Review: Patient Identification Technologies

Synthesizing the Evidence

The evidence was not pooled statistically because of the heterogeneity of the included studies, and a narrative synthesis was performed. The methodologist extracted the data and summarized them in evidence tables (see Appendix 2B in the original guideline document).

Systematic Review: Checklists

Synthesizing the Evidence

The evidence was not pooled statistically because one study was included. The methodologist extracted the data and summarized them in evidence tables (see Appendix 2C in the original guideline document)

Systematic Review: Scheduling Models

Synthesizing the Evidence

Only one study was included after full text review. The methodologist extracted the data and summarized them in evidence tables (see Appendix 2D in the original guideline document).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Development and Internal Review

This Evidence-based Series (EBS) report was developed by the Program in Evidence-based Care (PEBC), Cancer Care Ontario (CCO), and the CCO Systemic Treatment and Nursing Programs. The series is a convenient and up-to-date source of the best available evidence on the safe administration of chemotherapy developed through review of the evidentiary base, evidence synthesis, and input from external review participants in Ontario.

The EBS guidelines developed by the CCO PEBC use the methods of the Practice Guidelines Development Cycle.

The Working Group considered areas of interest that spanned the whole chemotherapy administration process and those specific to individual steps of the process. For each area of interest, the Group used specific questions to guide the search for evidence and to address topics of relevance to the recommendations.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Report Approval Panel (RAP) Review and Approval

Prior to the submission of this Evidence-based Series (EBS) draft report for External Review, the report was reviewed and approved by the Program in Evidence-based Care (PEBC) RAP, a panel that includes oncologists and whose members have clinical and methodological expertise.

External Review by Ontario Clinicians and Other Experts

The PEBC external review process is two-pronged and includes a targeted peer review that is intended to obtain direct feedback on the draft report from a small number of specified content experts and a professional consultation that is intended to facilitate dissemination of the final guidance report to Ontario practitioners.

Following the review and discussion of Section 1: Recommendations and Section 2: Evidentiary Base of this EBS and the review and approval of the report by the PEBC RAP, the Safe Administration of Systemic Treatment Expert Panel circulated Sections 1 and 2 to external review participants for review and feedback.

Methods

Targeted Peer Review

During the guideline development process, 10 targeted peer reviewers from Ontario and British Columbia considered clinical and/or methodological experts on the topic were identified by Safe Chemotherapy Administration Working Group. Several weeks prior to completion of the draft report, the nominees were contacted by email and asked to serve as reviewers. Four reviewers agreed and the draft report and a questionnaire were sent via email for their review. The questionnaire consisted of items evaluating the methods, results, and interpretive summary used to inform the draft recommendations and whether the draft recommendations should be approved as a guideline. Written comments were invited. The questionnaire and draft document were sent out on April 2, 2012. Follow-up reminders were sent at two weeks (email) and at four

weeks (telephone call). The safe administration of systemic cancer treatment Expert Panel reviewed the results of the survey.

Professional Consultation

Feedback was obtained through a brief online survey of healthcare professionals who are the intended users of the guideline. All oncology nurses, pharmacists and medical oncologists from Ontario, Quebec, Alberta and British Columbia in the PEBC database were contacted by email to inform them of the survey. Participants were asked to rate the overall quality of the guideline (Section 1 in the original guideline document) and whether they would use and/or recommend it. Written comments were invited. Participants were contacted by email and directed to the survey website where they were provided with access to the survey, the guideline recommendations (Section 1 in the original guideline document) and the evidentiary base (Section 2 in the original guideline document). The notification email was sent on April 12, 2012. The consultation period ended on May 23, 2012. The Safe Administration of Systemic Cancer Treatment Expert Panel reviewed the results of the survey.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

Most of the guidelines identified during the environmental scan for Part 1 were *not evidence based* but that evidence base was rarely randomized controlled trials. Most of the recommendations are based on expert opinion, because applicable evidence was not available.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Safe administration of systemic cancer therapy
- Prevention of errors during chemotherapy ordering, transcribing, dispensing, and patient identification

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- The Working Group values patient-centered care and believes that empowered patients can help in the delivery of safer care. The Working Group also values giving freedom to individual institutions to implement recommendations in a manner that is best suited for their specific contexts. Therefore, the recommendations provided are general directions without specific details. However, in recognition of the complexity of the administration of chemotherapy, and of the need for some guidance on detailed procedures, a COMPENDIUM of example procedures and requirements is provided in Section 2, Appendix 1 in the original guideline document that can be used and evaluated independently. The recommendations are hyperlinked with the examples in the compendium.
- Care has been taken in the preparation of the information contained in this report. Nonetheless, any person seeking to apply or consult the report is expected to use independent medical judgment in the context of individual clinical circumstances or seek out the supervision of a qualified clinician. Cancer Care Ontario makes no representation or guarantees of any kind whatsoever regarding the report content or use or application and disclaims any responsibility for its application or use in any way.

Implementation of the Guideline

Description of Implementation Strategy

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Quick Reference Guides/Physician Guides

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Jul 9

Guideline Developer(s)

Program in Evidence-based Care - State/Local Government Agency [Non-U.S.]

Guideline Developer Comment

The Program in Evidence-based Care (PEBC) is a Province of Ontario initiative sponsored by Cancer Care Ontario and the Ontario Ministry of Health and Long-Term Care.

Source(s) of Funding

The Program in Evidence-based Care (PEBC) is a provincial initiative of Cancer Care Ontario supported by the Ontario Ministry of Health and Long-Term Care. All work produced by the PEBC is editorially independent from its funding source.

Guideline Committee

Safe Administration of Systemic Cancer Treatment Expert Panel

Composition of Group That Authored the Guideline

Expert Panel Members: M. Leung, R. Bland, F. Baldassarre, E. Green, L. Kaizer, S. Hertz, J. Craven, M. Trudeau, A. Boudreau, M. Cheung, S. Singh, V. Kukreti, R. White

Financial Disclosures/Conflicts of Interest

In accordance with the Program in Evidence-based Care (PEBC) Conflict of Interest (COI) Policy, the guideline authors, members of the Nursing and Systemic Treatment Program, and internal and external reviewers were asked to disclose potential conflicts of interest.

Among the members of the working group, Dr. Simron Singh declared having received research support and honoraria from Novartis; Dr. Vishal Kukreti declared having received a grant for research on bar-coding for the safe administration of chemotherapy from the National Cancer Institute of Canada. All the other members of the working group declared no conflict of interest.

Among members of the Expert Panel, Venetia Bourrier declared to have received educational grants exceeding CAD$5,000 from pharmaceutical industry for the pharmacy department, to have received research support (co-investigator) for a study on improving the safety of ambulatory intravenous (IV) chemotherapy in Canada by CPSI and Cancer Services, and to be cancer care Manitoba director of the provincial oncology drug program.

None of the members of the Report Approval Panel and of the PEBC declared a conflict of interest.

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Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.

Availability of Companion Documents

The following are available:

- Leung M, Bland R, Baldassarre F, Green E, Kaizer L, Hertz S, Craven J, Trudeau M, Boudreau A, Cheung M, Singh S, Kukreti V, White R, Safe Administration of Systemic Cancer Treatment Expert Panel. Safe administration of systemic cancer therapy. Introduction and general methods. Toronto (ON): Cancer Care Ontario; 2012 Jul 9. 22 p. (Evidence-based series; no. 12-12 methods). Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario (CCO) Web site .
- Safe administration of systemic cancer therapy. Part 1: safety during chemotherapy ordering, transcribing, dispensing, and patient identification. Summary. Toronto (ON): Cancer Care Ontario; 2012 Jul 12. 13 p. Electronic copies: Available in PDF from the CCO Web site .
- Program in evidence-based care handbook. Toronto (ON): Cancer Care Ontario (CCO); 2012. 14 p. Electronic copies: Available in PDF from the CCO Web site .

In addition, Appendix 1 of the original guideline document includes a compendium of examples of procedures relevant to chemotherapy administration.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on September 6, 2013.

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